

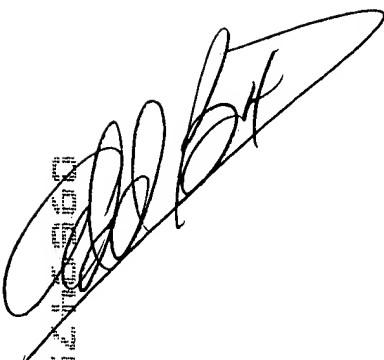
Claims:

1. A method for identifying genes which are up- or down-regulated in intestinal tissue of patients who have, or are at risk of developing, an inflammatory bowel disease or disorder, comprising:  
5           (i) generating a first library of nucleic acid probes representative of genes expressed by intestinal tissue of an animal without apparent symptoms and/or risk for an inflammatory bowel disease or disorder;  
10           (ii) generating a second library of nucleic acid probes representative of genes expressed by intestinal tissue of an animal which has symptoms of, and/or is at risk for developing, an inflammatory bowel disease or disorder; and  
15           (iii) identifying genes that are up- or down-regulated, e.g., by at least a predetermined fold difference, in the second library of nucleic acids relative to the first library of nucleic acids.
- 15       2. The method of claim 1, including the further step of cloning those genes which are up- or down-regulated.
- 20       3. The method of claim 1, including the further step of generating nucleic acid probes for detecting the level of expression of those genes which are up- or down-regulated.
- 25       4. The method of claim 1, including the further step of providing kits, such as microarrays, including probes for detecting the level of expression of those genes which are up- or down-regulated.
- 30       5. A method for determining the phenotype of a cell, particularly a cell of intestinal origin, comprising detecting the differential expression, relative to a normal cell, of at least one gene shown in Table 1 (herein the "IBD gene set"), or other IBD genes identified according to the method of claim 1.
- 35       6. The method of claim 5, wherein the assay detects a difference in the level of expression of an IBD gene of at least a factor of two.
- 40       7. The method of claim 5, which is used to assess a patient's risk of having, or developing, an inflammatory bowel disease.
- 45       8. A kit for assessing a patient's risk of having or developing an inflammatory bowel disease, comprising (i) detection means for detecting the differential expression, relative to a normal cell, of at least five genes shown in Table 1 (herein the "IBD gene set") or the gene products thereof; and (ii) instructions for correlating the differential expression of IBD genes or gene products, if any, with a patient's risk of

- having or developing an inflammatory bowel disease.
9. The kit of claim 8, wherein the detection means includes nucleic acid probes for detecting the level of mRNA of the IBD genes.
10. The kit of claim 8, wherein the detection means includes nucleic acid probes for detecting the presence of mutations or changes in methylation patterns to genomic sequences encoding the IBD genes.
11. The kit of claim 8, wherein the detection means includes an immunoassay for detecting the level of IBD gene products.
12. A method of doing a business for assessing a patient's risk of having or developing an inflammatory bowel disease, comprising (i) providing a service for determining the level of expression of an IBD gene set or gene products thereof, and comparing the level of expression to a normal cell; and (ii) assessing a patient's risk of having or developing an inflammatory bowel disease, if any, by determining the correlation between the differential expression of IBD genes or gene products with known changes in expression of IBD genes measured in other patients' suffering from an inflammatory bowel disease.
13. A method for treating a patient who has developed, or is at risk of developing, an inflammatory bowel disease comprising:
- (i) detecting the differential expression, relative to a normal cell, of at least one IBD gene;
- (ii) proscribing a course of treatment dependent on the level of expression of the IBD gene(s) relative to normal cells.
14. A nucleic acid array comprising a solid support and displayed thereon nucleic acid probes which selectively hybridize to at least 25 different IBD genes.
15. The array of claim 14, wherein the solid support is selected from the group consisting of paper, membranes, filters, chips, pins, and glass.
16. A drug screening assay comprising
- (i) administering a test compound to an animal having an inflammatory bowel disease, or a cell composition isolated therefrom;
- (ii) comparing the level of IBD gene expression in the presence of the test compound with one or both of the level of IBD gene expression in the absence of the test compound or in normal cells;

wherein test compounds which cause the level of expression of one or more IBD genes to approach normal are candidates for drugs to treat inflammatory bowel diseases.

17. A method for treating an animal having an inflammatory bowel disease comprising administering a compound identified by the assay of claim 16.
- 5  
18. A pharmaceutical preparation for treating an animal having an inflammatory bowel disease comprising a compound identified by the assay of claim 16 and a pharmaceutically acceptable excipient.

A handwritten signature in black ink, appearing to read "Brian K. Smith". The signature is written in a cursive style with a large, stylized 'B' at the beginning.

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